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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/771,872

02/04/2004

Carina Horn

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EXAMINER

ALEXANDER, LYLE

ART UNIT

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1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/771,872	Applicant(s) HORN ET AL.	
	Examiner Lyle A. Alexander	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/29/09</u> . | 6) <input type="checkbox"/> Other: _____ |

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 7,378,255.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to redox method using NBD to determine the analyte of interest.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-11 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Horn et al. (USP 7,378,255).

Horn et al. teach fluorimetric method and reagent for detecting an analyte by a redox reaction using NBD that is substantially identical to the instant claims. Horn et al. qualifies as prior art because the inventive entity is different from the instant application.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cass et al. (USP 6,312,906).

Cass et al. teach a method of detecting a biological analyte using "4-nitrobenzo-2-oxa-1,3-diazol" (NBD hereafter) as an indicator (see column 8 line 38) that is visualized by fluorescent light emissions. The taught "4-nitrobenzo-2-oxa-1,3-diazol" has been read on the claimed indicator.

The 9/25/08 amendments have added language in the body of the claim "causing a redox reaction ... performing a fluorimetric determination ... as a result of the redox reaction ...". The Office maintains Cass et al. performs the same steps of adding the NBD to a sample to indicate the presence of an analyte and performs a fluorimetric determination to determine the analyte. The Office maintains the claims are indistinguishable from Cass et al.

Applicants may consider including the step of adding the component required to accomplish the redox reaction.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lakowicz (2002/0160400), Albarella et al. (USP 6,872,573), Hoenes(USP 5,334,508) or Ghosh et al.(USP 4,358,595).

Lakowicz teaches a method of detecting biological analytes, such as glucose, etc. using "7-nitrobenzo-2-oxa-1,3,-diazol-4-yl" as an indicator that is visualized by

fluorescent light emissions. The taught "7-nitrobenzo-2-oxa-1,3,-diazol-4-yl" has been read on the claimed indicator. Additionally, because the same analytes are detected (e.g. glucose), the reactions meet the claimed limitation of being a redox reaction.

Albarella et al., Hoenes and Ghosh et al. all teach fluorescent labels that are indistinguishable from the claimed compound. Albarella et al. teach the addition of cupric compounds and Hoenes oxidoreductase which are reducing agents and cause a redox reaction.

The 9/25/08 amendments have added language in the body of the claim "causing a redox reaction ... performing a fluorimetric determination ... as a result of the redox reaction ...". The Office maintains the above references perform the same steps of adding the NBD to a sample to indicate the presence of an analyte and performing a fluorimetric determination to determine the analyte. The Office maintains the claims are indistinguishable from the cited prior art.

Response to Arguments

Applicant's arguments filed 11/8/07 have been fully considered but they are not persuasive.

Applicants' state the cited prior art fails to teach the claimed redox methods using NBD fluorescent markers. Even in light of the 9/25/08 amendments, there is no step of adding an additional reagent to accomplish the claimed redox reaction. As presently claimed, the method only requires the addition of the sample to NBD and subsequent

fluorimetric analysis. The Office maintains the above rejection meet all of these limitations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Tuesday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lyle A Alexander/
Primary Examiner, Art Unit 1797

Lyle A Alexander
Primary Examiner
Art Unit 1797